

OMIC DIGEST

Ophthalmic Risk Management Digest

Compounded Products: Use, Regulation, and Risk

By Kimberly Wynkoop
OMIC Legal Counsel

The recent meningitis outbreak and resulting patient deaths have driven compounding pharmacies into the spotlight, with calls for greater federal government oversight and regulation. This article will explore the role compounding pharmacies play in the delivery of drugs in our health care system, their regulation, and the issues that may lead to change in this supply mechanism.

The Food and Drug Administration (FDA) considers pharmacy compounding "the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized medical needs of an individual patient." This traditionally has been done for medically necessary reasons, such as avoiding a non-essential ingredient due to patient allergy, or voluntary reasons, such as adding flavor to a child's medication. More and more, however, other factors have influenced the demand for compounded products. One is the shortage of brand-name drugs from FDA-approved manufacturers. Another factor is price. Compounding pharmacies often charge much lower prices than major manufacturers for essentially the same product.¹ These clinical factors have driven many pharmacies out of traditional one-off compounding to larger scale production.

While physicians are granted broad discretion in prescribing drugs for individual patients, whether off-label, unapproved, or customized, the manufacturing and distribution of drugs is more strictly controlled. With typically manufactured drugs, the FDA has broad regulatory oversight. Compounding, however, falls in a grey area where oversight is shared. Like traditional pharmacies, compounding pharmacies are regulated by state boards of pharmacy, which oversee all aspects of licensure and adherence to practice requirements. These requirements vary by state. For instance, some states allow compounding pharmacies to fill general prescriptions for "office use," while others strictly require a patient-specific prescription for each substance compounded and supplied.

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MESSAGE FROM THE CHAIRMAN



As members of the American Academy of Ophthalmology, OMIC insureds are aware of the ongoing mutually supportive relationship between the Academy and OMIC. This successful collaboration is rooted in a deep shared commitment to excellence in patient care, patient protection and safety, liability risk mitigation, and improved physician performance. The tangible results of this commitment can be seen in the jointly produced educational programs, print and electronic products, online courses, webinars, and traveling seminars. These educational products are made available to all ophthalmologists whether or not they insured by OMIC.

Nowhere is the benefit of this unique collaboration more evident than in a new online continuing medical education activity jointly developed by the Academy Committee for Practice Improvement (CPI), chaired by Joseph Caprioli, MD, FACS, and the OMIC Risk Management Committee, chaired by Tamara R. Fountain, MD. *Building Best Practices for Informed Consent* has been in development for several years and is based upon the Academy/OMIC jointly developed *Practice Guidelines for Informed Consent* published in 2010.

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Eye on OMIC

OMIC

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Reception Draws Big Crowd to OMIC Booth at AAO Meeting

OMIC's silver anniversary reception was a great success thanks to the estimated 700 ophthalmologists who helped us celebrate 25 years in business during the 2012 Annual Meeting of the American Academy of Ophthalmology. The event immediately followed the OMIC Forum, which recounted our top ten indemnity payments and attracted one of the largest audiences in the company's history. In addition to serving refreshments, OMIC announced the winners of our Apple iPad drawing at the reception. Congratulations to OMIC policyholder Keith Kellum, MD, of Houma, Louisiana, and applicant Amin Ashrafzadeh, MD, of Modesto, California. Photos of the event can be viewed at www.omic.com. OMIC wishes to thank all of the ophthalmologists who have put their trust

in us since we opened for business a quarter century ago. Our success is the direct result of your support. For a timeline of major milestones in OMIC's history, please download the *2012 Members Report* at www.omic.com or visit OMIC's facebook page at <http://facebook.com/OMICpage>.

OMIC Now a Quarter Billion Dollar Company

In recent months, we achieved another milestone—passing a quarter billion dollars in net admitted assets. During the past decade, OMIC has ranked above all other malpractice carriers in the United States for financial stability, specifically the company's operating and combined ratios. OMIC's premium to surplus ratio places it among the most fiscally sound insurance companies in America. This profitable operating performance is the result of our insureds' favorable claims experience, and it allows us to consistently declare above average policyholder dividends—nearly \$40 million to date.

Message from the Chairman

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Practice Guidelines guides ophthalmologists through a quality informed consent process that emphasizes assessment and communication. *Building Best Practices* picks up with the implementation of the informed consent process. There are several steps and resources in this online activity to help ophthalmologists ensure that their informed consent process is organized, consistent, and thorough:

- **Chart review checklists** to test if a practice has appropriate informed consent education and documentation to ensure that best practices are followed during the consent process.
- **Multiple choice self-assessments** to test knowledge of informed consent requirements based on *Practice Guidelines for Informed Consent*.
- **Procedure-specific consent forms** developed by OMIC that can be customized to fit specific practice needs.
- **Supplemental materials on informed consent**, including OMIC closed claims studies, available at www.omic.com.

This online activity is ideal for new practices looking to establish an organized and consistent informed consent system as well as established practices that want to reexamine

and strengthen their existing informed consent process. The Academy will provide up to 20 AMA PRA Category 1 Credits™ and OMIC insureds will receive a risk management premium discount for participation in *Building Best Practices*.

This is the second online performance improvement continuing medical education activity jointly developed by the Academy CPI and OMIC. The first, in 2009, was the *Wrong Site Wrong IOL* course, which utilizes video reenactments to demonstrate where errors can occur and provides clinical guidelines to prevent operating room mistakes related to wrong surgical site, wrong patient, and wrong IOL implant. Hundreds of Academy members in the United States and around the world have participated in this course.

The Academy CPI's mission to develop educational activities that provide tools and a framework for evaluating and improving practices is a good fit with OMIC's mission of providing risk management education that reduces the risk of patient injury and malpractice claims. The ultimate goal of both organizations is to assist ophthalmologists with providing the best possible care for their patients.

John W. Shore, MD
Chairman of the Board



Liability and Coverage for Contaminated-Product Claims

By Kimberly Wynkoop
OMIC Legal Counsel

As detailed in the lead article, the plethora of meningitis cases due to contaminated steroid injections has put compounding pharmacies under the microscope. Physicians are also being scrutinized for their part in prescribing and administering the tainted drugs. This article will look at ophthalmologists' potential liability and the coverage OMIC's policy provides should an OMIC insured be sued for prescription or use of contaminated compounded products.

As of November 7, 2012, 28 lawsuits in states from Minnesota to Florida had been filed against the New England Compounding Center ("NECC"), the pharmacy that compounded the steroids in the meningitis cases. Not only have the NECC corporate entity and executives been named as defendants, plaintiffs looking for deeper pockets are suing the physicians and clinics who supplied and administered the tainted injections.

Ophthalmologists use compounding pharmacies for a variety of products, including bevacizumab, Brilliant Blue-G (BBG), triamcinolone acetonide, and 5 percent Betadine. Compounded Trypan Blue, BBG, and Avastin have all been implicated in outbreaks of endophthalmitis. While no cases of ophthalmic injury from NECC products have been reported, its compounded betamethasone suspension was recalled due to potential contamination.

If a physician is named in a contaminated-product lawsuit, potential liability will depend on whether the plaintiff alleges product liability or professional liability ("medical malpractice") and whether

the court finds those claims applicable to the physician. Most state's product liability laws provide for strict liability, which means a defendant can be held responsible without proof of fault. With strict product liability, all people or entities in the distribution chain are potentially liable. However, under some state's laws, product liability claims against health care providers are not permitted. Product liability claims can also be based on negligence. A finding of negligence requires that the defendant breached a duty owed to the plaintiff, which caused the plaintiff to suffer damages.

There are three types of product liability defects: manufacturing, design, and failure to warn. A manufacturing defect occurs when the product is different than its design due to the manufacturing process. This includes contamination of the product during compounding as occurred at NECC.

A design defect means that the actual intended design of the product makes it unreasonably dangerous. In drug cases this usually means unreasonably severe side effects.

Failure to warn defects, also called marketing defects, occur when a product has improper or insufficient labeling, instructions, safety warnings, or recommendations for use. These marketing omissions can occur at the manufacturer, pharmacist, or provider level and often require a finding of negligence. The prescribing provider and even ancillary staff who instruct the patient on proper use of a drug or device may be liable as "learned intermediaries" between a drug's manufacturer (or compounder) and the patient.

Medical malpractice, unlike product liability, always requires a finding of negligence. In this case, the breach of duty applies to the provision of medical services to the patient, not the sale of products. Therefore, in order for the court to determine whether product liability or malpractice should apply to a claim, it may attempt to

determine if the provider "sold" the product. One way the court could do so is to look at the medical bills. Separate prices for the service (e.g. an injection) and the product (e.g. a steroid) could indicate a sale, whereas a global service charge or non-itemized bill would suggest a service.

If the prescription or administration of the contaminated product is considered a service, the plaintiff must show that the provider was negligent. For instance, did the provider fail to investigate the safety of the product being prescribed? Did the physician not obtain proper informed consent by failing to discuss all of the risks that went along with the use of the product? If the plaintiff can prove the physician breached this duty of care and the patient was harmed, the physician will be liable.

OMIC does not exclude coverage for an ophthalmologist's prescription or use of compounded drugs or devices. OMIC respects the provider's prerogative to select the most appropriate drug or device for a particular procedure or treatment for an individual patient even if it is off-label, unapproved, or compounded. OMIC's policy covers insureds for allegations of medical malpractice based on an ophthalmologist's direct patient treatment. This includes the prescribing or dispensing of medical supplies, devices, and drugs, including compounded products. However, OMIC's policy does not cover product liability claims; it expressly excludes claims based on the designing, producing, manufacturing, assembling, distributing, marketing, or selling of any medical device or other product, including the failure to provide warnings or instructions with the product. If ophthalmologists will be reselling or otherwise participating in the distribution of products beyond direct patient treatment, they should secure separate coverage for product liability on a stand-alone basis or as part of a general liability package.

Compounded Products: Use, Regulation, and Risk

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The federal government's authority over compounding pharmacies is more complicated. The FDA has the authority to inspect compounding pharmacies to ensure the drugs and active pharmaceutical ingredients they use are safe. But what about FDA control over the finished product? The Food, Drug, and Cosmetic Act (FDCA) establishes FDA jurisdiction over "new drugs." The FDA's position, with supporting judicial authority, is that compounded drugs fall under the new drug definition. As "new drugs," the FDCA generally prohibits compounded drugs from being introduced into interstate commerce since they lack any FDA finding of safety and efficacy. Despite the unapproved status of compounded drugs, the FDA has long recognized that traditional pharmacy compounding serves an important public health function and has not often enforced this prohibition.

Compounded Trypan Blue and Avastin Contaminated

However, instances of compounded drugs endangering public health have given rise to concern within the FDA. One such instance occurred in 2005 at a Washington, DC, Veterans Administration hospital where bacteria-contaminated Trypan Blue Ophthalmic Solution, compounded for use in cataract surgery, blinded two patients and damaged vision in several others. A more recent example: In the summer of 2011, at least a dozen patients in the Miami area contracted streptococcus endophthalmitis from tainted compounded Avastin.

The FDA may not necessarily know about all instances of public harm since, unlike commercial drug manufacturers, pharmacies aren't required to report adverse events associated with their products. The Limited FDA Survey of Compounded Drug Products, published in 2006, found quality problems in compounded drugs, including potency issues and contamination.

The active pharmaceutical ingredients passed inspection, so the failures of the finished drug products were considered likely due to the compounding processes themselves. The FDA concluded that, given their widespread use and the potential for serious injury, the quality of compounded drugs constitutes an important public health concern.

Adding to the complexity of federal regulation of compounding pharmacies, there are two different analyses for regulation depending on the applicable judicial circuit. In 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA), which added section 503A to the FDCA exempting compounded drug products from the adulteration, misbranding, and new drug provisions of the FDCA as long as certain requirements were met. In 2002, the US Supreme Court found that some of the requirements for the exemptions were unconstitutional. The Fifth Circuit Court of Appeals thereafter ruled that this didn't invalidate the rest of section 503A. So in the Fifth Circuit (Texas, Louisiana, and Mississippi), the FDA applies the section 503A exemptions.

In the rest of the United States, the FDA maintains its original reach and does not apply section 503A. Instead, it follows the revised FDA compliance policy guide (CPG) on pharmacy compounding. The CPG sets forth a non-exhaustive list of nine factors (many drawn from Section 503A) that the FDA considers in determining whether to take enforcement action against a pharmacy when the scope and nature of its activities raise the kind of concerns ordinarily associated with drug manufacturing. These factors include the compounding of drug products that (1) have been pulled from the market because they were found to be unsafe or ineffective; (2) are essentially copies of commercially available drug products; or (3) were compounded in advance of receiving prescriptions, except in very limited quantities relating

to the amounts of drugs previously compounded based on valid prescriptions.

Through the CPG, the FDA assures compounding pharmacies that its main concern is those pharmacies that are effectively engaging in multi-patient "manufacturing" under the guise of compounding. The FDA prioritizes enforcement actions related to compounded drugs using a risk-based approach, giving the highest enforcement priority to pharmacies that compound products that are causing harm or that amount to health fraud. However, the FDA has recently stated that this doesn't mean that the FDA will take enforcement action only if the agency identifies a particular safety problem. It may also take action when copies of FDA-approved drugs are being created in large volumes for no apparent medical need.

Brilliant Blue G Linked to 33 Endophthalmitis Cases

A look at the recent Brilliant Blue G recall provides insight into how the FDA is applying its enforcement discretion and the factors it is taking into consideration. In Los Angeles in March 2012, nine cases of fungal endophthalmitis were diagnosed in patients who had undergone vitrectomies with epiretinal membrane peeling using the Brilliant Blue-G (BBG) dye from Franck's Compounding Lab ("Franck's") in Ocala, Florida. Local and state health departments, the Centers for Disease Control and Prevention (CDC), and the FDA collaborated in the investigation. It was expanded to include injectable drug products containing triamcinolone due to reports of eye infections in patients who received it during eye surgery. As of April 30, 2012, there were a total of 33 endophthalmitis cases in seven states. In May, the CDC advised health care providers to avoid use of any compounded products labeled as sterile from Franck's during the ongoing investigation.



The FDA issued a warning letter to Franck's on July 9, 2012, based on its March-May inspection of the lab. The FDA identified various microorganisms in samples of the compounded BBG that matched the clinical isolates from patients who developed fungal endophthalmitis. Multiple bacterial and fungal species were found at Franck's in several locations where sterile drugs were compounded and other unsanitary conditions were also identified. The FDA determined that Franck's BBG injection drug product was adulterated under the FDCA due to the contaminants present. Further, this drug and all sterile drugs compounded by Franck's were found to be adulterated in that they were prepared, packed, or held under unsanitary conditions. The FDA also concluded that the BBG products were misbranded because their labeling was false or misleading since the drugs were labeled incorrectly as being sterile. The FDA advised Franck's that failure to promptly correct these deficiencies could result in legal action. In May, Franck's stopped compounding sterile drugs.

NECC's Ophthalmic Drugs Also Under Scrutiny

Only four months later, a new illness outbreak based on compounded drugs quickly overshadowed the BBG debacle and precipitated intense scrutiny of the compounding industry. What began as a single reported case of meningitis September 21, 2012, in Tennessee, has burgeoned, according to the CDC's November 19, 2012, report, to 490 cases of fungal disease, including 34 deaths spread across 19 states — all linked to contaminated epidural steroid injections compounded by the New England Compounding Center (NECC), Framingham, Massachusetts. The CDC traced the meningitis outbreak to three lots of the compounded steroids that were distributed to 75 medical facilities in 23 states, affecting as many as 14,000 patients. On October 15, 2012,

the FDA further advised health care providers to follow-up with patients who received any NECC injectable product after May 20, 2012, including injectable ophthalmic drugs and those used in conjunction with eye surgery.

The recalls and investigation have been a coordinated effort between the NECC, FDA, CDC, and Massachusetts Department of Public Health (DPH) Board of Registration in Pharmacy, which has state regulatory authority over the NECC. At the request of the DPH, the NECC agreed to voluntarily surrender its license to operate during the investigation; it now has been permanently revoked. The DPH Board of Pharmacy report released October 23, 2012, identified serious deficiencies and significant violations of pharmacy law and regulations by the NECC. Evidently, the NECC solicited bulk orders and distributed large quantities of product for general use rather than requiring a prescription for each individual patient as state law requires. The NECC did not follow proper sterilization standards and shipped some orders of drugs before waiting for the final results of sterility testing. The Board found many unsanitary conditions at the NECC site as well.

The meningitis outbreak, following shortly on the heels of the BBG endophthalmitis cases, has prompted health officials and lawmakers to call for immediate changes in the oversight of compounding pharmacies arguing that, because no one entity has full responsibility for overseeing compounding pharmacies, they essentially slide through the cracks. The Governor of Massachusetts has already declared that the state will begin making unannounced inspections of pharmacies that prepare injectable medications and require that they submit annual reports detailing what they produce, how much, and where it is distributed. As of November 19, 2012, fifteen states were implementing new, or increasing

enforcement of existing, regulations on compounding pharmacies. These states require an individual patient prescription for every compounded medication order. This concerns the American Academy of Ophthalmology and American Society of Retina Specialists because it limits an ophthalmologist's ability to purchase bulk quantities of commonly-used compounded ophthalmic drugs. These groups are working together to keep the focus of reform on improved patient safety (i.e., sterility issues), rather than distribution regulations that have the potential to limit drug availability.

On the federal level, Congress is investigating the outbreaks and is considering legislative action to strengthen federal drug safety regulations. On November 1, 2012, the VALID Compounding Act was proposed to preserve state regulatory authority over traditional small compounding pharmacy activities, while ensuring that compounding pharmacies operating as drug manufacturers are regulated by the FDA.

Lawsuits against the NECC and its executives have been filed in several states and patients have begun suing their providers as well. As we have seen in the cases of Trypan Blue, Avastin, BBG, and the NECC's ophthalmic products, the drugs and devices that ophthalmologists obtain from compounding pharmacies are not without risk. Please see the **Policy Issues** article for a discussion of liability risks and policy coverage and the **Hotline** article for steps ophthalmologists can take to limit their liability and minimize the risks to the patients they treat when utilizing compounding pharmacies.

1. For example, compounding pharmacies provide a much cheaper version of the brand named drug Makena (used to reduce the risk of premature births). Once the drug got FDA approval, its manufacturer charged 100 times more than compounders. The FDA wanted to ban compounded versions on the grounds that Makena had met the FDA's rigorous safety standards, but senior Obama officials concerned about price halted the ban.



Closed Claim Study

Injection of Anecortave Acetate into Globe during ARMD Risk Reduction Trial

By Ryan Bucsi, OMIC Senior Litigation Analyst

ALLEGATION

Negligent administration of Anecortave Acetate into globe.

DISPOSITION

Drug manufacturer indemnified OMIC insured and settled claim for \$500,000.

Case Summary

A 75-year-old female was diagnosed with wet macular degeneration and treated with photodynamic therapy and intravitreal Kenalog. Subsequently, she developed a massive subretinal hemorrhage secondary to age-related macular edema in the right eye. The left eye also had high-risk macular drusen. A non-OMIC-insured ophthalmologist recommended that the patient participate in an age-related macular degeneration risk reduction trial, as he felt there was no other treatment currently available that would be of benefit to the left eye. An OMIC insured performed eight injections of Anecortave Acetate under the trial protocol.

During the last procedure, the insured applied Xylocaine on a Q-tip to the conjunctival surface superotemporally, approximately 8 mm back from the limbus. Xylocaine was then injected about 8mm posterior to the limbus superotemporally. While waiting for the anesthesia to take effect, he pushed the medication through the cannula to the appropriate mark on the syringe. One additional drop of topical anesthetic was applied and the lid speculum was inserted. The insured marked the spot using calipers on the slightly elevated conjunctiva that was 8 mm posterior to the limbus superotemporally. The insured then used grasping forceps to pinch the slightly elevated conjunctiva and make a small snip in the conjunctiva and tenons capsule. A fair amount of scarring was encountered as he tried to dissect down to the sclera surface. The insured was able to insert a cannula but upon withdrawing the tip he noticed a clear strand of material. The insured suspected it was vitreous and realized at this point that the medication had been injected into the globe. A non-OMIC insured retinologist subsequently performed a vitrectomy to remove the Anecortave with silicone oil tamponade and silicone removal OS along with epiretinal membrane peeling. The macula was stable; however, the prognosis for visual recovery was uncertain. The patient's visual acuity remained at 20/200 OS despite cataract surgery.

Analysis

The OMIC insured was adamant that he did not deviate from the standard of care during the final trial injection. It was the insured's opinion that the previous injections were responsible for the scarring. The insured reported to his attorney that he had discovered reports of several other patients who experienced similar complications. As discovery progressed, the drug manufacturer abandoned the treatment as it became apparent that it was not beneficial to patients. Prior to the drug trial, the OMIC-insured had obtained a specific indemnification agreement covering this type of incident. OMIC's defense attorney approached the manufacturer's attorney about this agreement; however, the attorney for the manufacturer maintained that there was no indemnification since the proposed claim was for alleged negligence by the OMIC insured. Defense counsel reminded this attorney that the agreement specifically spelled out that the manufacturer would indemnify the OMIC-insured in that context. The attorney for the manufacturer continued to disagree but allowed that the manufacturer, for professional relationship reasons, would indemnify the OMIC insured. The manufacturer recommended that defense counsel submit a formal demand for indemnification. The demand was accepted and the insured was dismissed from the claim. The drug manufacturer settled for \$500,000.

Risk Management Principles

The insured and the entity he was working for at the time of this incident were extremely thorough in drafting their agreement with the drug manufacturer prior to participating in the trial. By entering into a legally enforceable indemnification agreement with the drug manufacturer, the insured was able to avoid a large settlement. Ophthalmologists should indeed negotiate such agreements before they become involved in surgical and drug studies. Furthermore, the insured applied good technique throughout the trial and thoroughly documented his approach and technique during each injection. This documentation made it very difficult for the drug manufacturer to allege that the insured's technique was improper.

Risk Management Hotline



Reduce the Risk of Compounded Drugs

By Anne M. Menke, RN, PhD
OMIC Risk Manager

State and federal legislatures are reviewing changes in law to increase the safety of compounded drugs. Even before new laws and regulations go into effect, ophthalmologists can take action to reduce the risk of administering compounded drugs.

Q Am I required to use FDA-approved drugs instead of compounded ones?

A No. OMIC is not aware of any law that prevents physicians from choosing the drug or device they feel is in the best interest of their patient. Physicians should certainly be aware of whether there are FDA-approved medications available to treat the condition, and document the decision-making process that led to choosing one drug over another. Bear in mind that compounded drugs do not undergo the same premarket review for safety and efficacy as FDA-approved manufactured drugs.

Q What do I need to do to credential a compounding pharmacy?

A You need to perform due diligence by evaluating the compounding pharmacy's licensure, accreditation, and compliance with laws and regulations. First, check with the board of pharmacy in your state. Ask the pharmacy board to send you your state laws governing compounding pharmacies; this will help you determine if state law requires the pharmacy to be licensed in your state, and whether a patient-specific prescription is needed before ordering drugs. Ask the pharmacy board if it is aware of any concerns about the particular company. Second, determine whether the pharmacy has achieved voluntary accreditation by the

Pharmacy Compounding Accreditation Board (PCAB), an organization composed of eight of the nation's leading pharmacy organizations. Third, gather information about the compounding process. The IACP has created The Compounding Pharmacy Assessment Questionnaire ("CPAQ"), a comprehensive tool to help the medical community assess and select a compounding pharmacy. It is available online at www.iacprx.org. Ask the pharmacy if it complies with the United States Pharmacopeia Convention (a scientific nonprofit standard setting organization) 797 standards for the compounding, transportation, and storage of compounded sterile products.¹ Go in and actually meet the pharmacists and inspect the facility. Determine where the compounding pharmacy's raw products are obtained, if they are pharmaceutical grade for humans, and how batches are sorted and tested.² Ask what sample size the pharmacists use and whether they have sterility tests performed independently at an unaffiliated lab. Although price shopping is tempting, do not base your choice of pharmacy on cost alone.

Q What steps can my practice take?

A When ordering products, ask the compounding pharmacy to prepare the medication specifically for ophthalmic use, confirm the dose and sterility, identify the syringe suitable for the medication, provide storage and beyond-use instructions, and include a copy of the sterility tests with each order. Follow the storage and beyond-use instructions provided by the compounding pharmacy. Keep a log of medications that were compounded, and document the lot number in the patient's medical record so that you can easily contact affected patients in the event of a recall. Follow current clinical guidelines on the proper aseptic technique during the preparation and administration of injections. Report any suspected adverse events following use of compounded products to the FDA's MedWatch program at www.fda.gov/medwatch.

fda.gov/medwatch. For help with adverse events, recalls, and patient communications OMIC insureds are encouraged to contact OMIC's confidential Risk Management Hotline by calling (800) 562-6642, option 4.

Q Am I required to obtain informed consent to administer or use compounded drugs?

A Informed consent is generally required for procedures or treatments whose risks exceed those that a lay person with average knowledge of medical issues would understand. The standard is not what a physician feels a patient should know, but what a prudent layperson would want to know. Informed consent is thus not required for a simple x-ray, but would be for fluorescein angiogram since the dye can cause fatal, allergic reactions. In the case of medications, physicians are expected to obtain informed consent from patients by explaining the condition, the expected benefit from the medication, known complications, and available alternatives. If the drug is being used off-label, that information should be part of the consent process. Prior to the highly publicized meningitis cases discussed in the lead article, it is unlikely that ophthalmologists explained to patients where they obtained their drugs. In the current environment, some patients may ask, and most patients would probably want to know. While it is not necessary to obtain the patient's informed consent to use compounded drugs, be prepared to answer any questions patients may have about the issue. Practices and ambulatory surgery centers who use many compounded drugs may want to prepare an information sheet that explains what compounding is, and the steps the practice has taken to credential the compounding pharmacy.

1. Welcome to USP797.org, <http://usp797.org>.

2. Sellers S, Utian WH. "Pharmacy compounding primer for physicians: prescriber beware." *Drugs* 2012 Nov 12;72(16):2043-50.



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Calendar of Events

OMIC continues its popular risk management courses this fall and winter. Upon completion of an OMIC online course, CD/DVD, or live seminar, OMIC insureds receive one risk management premium discount per premium year to be applied upon renewal. For most programs, a 5% risk management discount is available; however, insureds who are members of a cooperative venture society (indicated by an asterisk*) may earn an additional discount by participating in an approved OMIC risk management activity. Courses are listed here and on the OMIC web site, www.omic.com.

Contact Linda Nakamura at (800) 562-6642, ext. 652, or lnakamura@omic.com for questions about OMIC seminars, CD/DVD recordings, or computer-based courses.

January

11 *Lessons Learned from Malpractice Claims.** Connecticut Society of Eye Physicians. Aqua Turf Club, Plantsville, CT; 3:50 pm. Register with CSEP at (860) 567-3787.

19 *Informed Consent and the Risks of Cataract Surgery: Telling It Like It Is to the Patient.* Ritz Carlton, Sarasota, FL; 3–4 pm. Register with the organizers at www.cssarasota2013.com.

20 *25 Years of Ophthalmic Claims: One State's Experience.* Hawaiian Eye 2013. Hilton Waikoloa Village, Big Island, Hawaii; 9:30–10:30 am. Register with Hawaiian Eye at <http://osnhawaiianeye.com/> or call (877) 307-5225, ext. 219.

February

3 *Malpractice Claims Studies.** Ohio Ophthalmological Society. Hilton Columbus at Easton Town Center, Columbus, OH; time TBA. Register with OOS at (614) 527-6799.

March

8 *Malpractice Claims Studies.** Illinois Association of Ophthalmology. Donald Stephens Convention Center, Rosemont, IL; time TBA. Register with the IAO at (847) 680-1666.

April

3–7 *OMIC Closed Claims.** American Association for Pediatric Ophthalmology & Strabismus. Westin Copley Place, Boston, MA; time TBA. Register with AAPOS at (415) 561-8505 or go to http://www.aapos.org/meeting/2013_annual_meeting/.

May

17–18 *OMIC Closed Claims.** Kentucky Academy of Eye Physicians & Surgeons. 21 C Hotel, Louisville, KY; time TBA. Register with KAEPS at <http://www.kyeyemds.org/>.

17–18 *OMIC Closed Claims.** Texas Ophthalmological Association. Henry G. Gonzalez Convention Center, San Antonio, TX; time TBA. Register with the TOA at (512) 370-1504 or go to <http://texaseyes.org/>.

OMIC will be closed December 24 through January 1. If you have an urgent matter and must speak to a staff member during this time, please call (800) 562-6642, ext. 609, and leave a message. Staff will return urgent calls in a timely manner. Non-urgent calls will be returned on Wednesday, January 2. The OMIC staff wishes you and your family a happy holiday.